



NDA 16-796/S-039

Akorn, Inc.
150 S. Wykles Road
Decatur, IL 62522

26 NOV 2001

Attention: Shahid Ahmed
Vice President, RA, QC & QA

Dear Mr. Ahmed:

Please refer to your supplemental new drug application dated November 14, 2001, received November 15, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Inapsine (droperidol) Injection.

This supplemental new drug application provides for changes to the package insert regarding incidence of potentially life threatening cardiovascular adverse events associated with use of this product.

We have completed the review of this supplemental application, and it is approved, with the agreed upon revision listed below, effective on the date of this letter.

CNS Depressant Drugs: Other CNS depressant drugs (e.g. barbiturates, tranquilizers, opioids and general anesthetics) have additive or potentiating effects with INAPSINE. Following the administration of INAPSINE, the dose of other CNS depressant drugs should be reduced.

The final printed labeling (FPL) must be identical, and include the revision indicated, to the submitted draft labeling (package insert dated November 14, 2001). This revision is a term of the approval of this application.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 16796/S-039." Approval of this submission by FDA is not required before the labeling is used.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Lisa Basham, Regulatory Project Manager, at (301) 827-7420.

Sincerely,

Cynthia G. McCormick, M.D.
Director
Division of Anesthetic, Critical Care, and
Addiction Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research